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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,528	12/02/2004	Josef Beden	P70195US0	4488

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EXAMINER	
CECIL, TERRY K	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,528	BEDEN ET AL.	
	Examiner	Art Unit	
	Mr. Terry K. Cecil	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-12-2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Pastrone et al. (U.S. 5,431,627), as evidenced by Pastrone U.S. Patent No. 4,927,411, incorporated by reference.

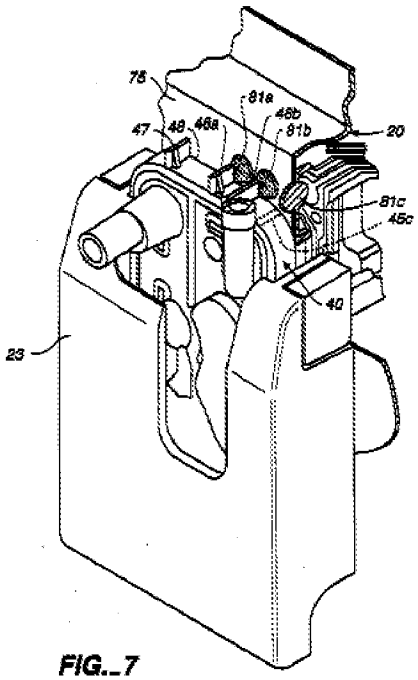


FIG._7

Regarding claims 1 and 3, Pastrone teaches a liquid treatment machine 20 including cassettes (30, 40, 50, 60) for different applications inserted therein. The cassettes have a rigid body (131, 133) and a foil (elastomeric member 133). The fitted chambers and passages of the cassette are best shown in figures 2-4 of U.S. Patent No. 4,927,411, incorporated by reference into Pastrone (col. 5, line 1-9). It is noted that it is the examiner's interpretation of claim 1 that only 1 cassette is required by the claim language (the recitation of "cassette*s*" is part of the intended use). However, figures 2-5 and 2A-5A of Pastrone depict different integration

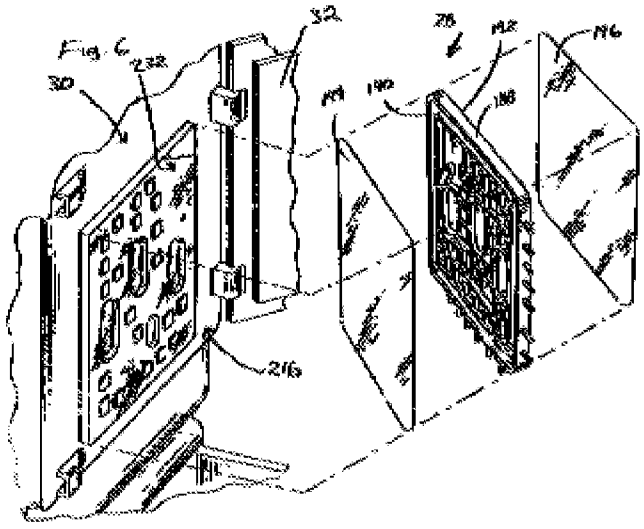
shapes (i.e. different interfacing configurations) resulting from the respective ID flag configurations.

As for claim 2, the cassettes are single use (col. 7, line 4) and are considered to be "disposable". As for claims 3 and 4, the drug delivery cassettes could be used for acute treatment, e.g. patent controlled delivery of analgesics for acute pain. As for claim 5, the rigid body is molded (see col. 3, line 43 of U.S. 4,927,411 incorporated by reference), wherein a portion thereof e.g. the area of leader of reference no. 34 in figure 2B can be considered a "handle".

As for claim 7, door 23 (figure 1) is fitted to a frame and the cassette is between the door and the "machine block" (e.g. 75).

As stated earlier, it is the Examiner's position that claim 1 only requires one liquid treatment machine and <u>one</u> cassette insertable therein. Therefor, describing the "one surface" of the cassette as a common basic variant to "all cassettes" fails to further structurally define the cassette. Applicant's claim 1 requires the cassette to have a plurality of surface regions (no distinction is given therebetween); one surface that includes components of actuators or sensors; and further surfaces containing actuators or sensors. Such limitations are anticipated by the Pastrone references including a plethora of sensors and actuators (see the abstracts thereof).

3. Claims 1-5, 7-9, 12-13, 20 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Westberg et al. (U.S. 7,195,607).



Westburg teaches a blood processing machine including a block 216 receiving a cassette 28 including a "foil" (194). The machine includes actuators (valve actuators PA1-PA4) and sensors (e.g. pressure sensors). It is the Examiner's position that the phrase "for the operation of the apparatus with the inserted cassette such that cassettes can be inserted in different integration shapes" to be an intended use of the apparatus and that claim 1 does not require one than one cassette nor is the cassette required to contact the sensors. As for claim 5, the edge 190 is considered to be a handle. A door 32 includes a latch 218, wherein the block includes a moveable bladder and gasket and programmable pneumatic actuator for pneumatically sealing the cassette between the door and machine block [as in claims 7-9]. The block 216 includes an elastic mat 232 having recesses therein [as in claims 12-13]. A venting chamber 316 is also taught [as in claim 20]. As for claim 27, the single needle is shown in figure 10.

See the italicized claim interpretation comments in the previous section. Westberg is considered to have the claimed plurality of surface regions and surfaces having components of sensors and actuators.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of Burbank et al. (U.S. 7,147,613). Burbank teaches a door sensor 32. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the sensor 32 of Burbank in the invention of Westburg, since such would provide the benefit of confirming the door is secured before enabling circulation.

6. Claims 14, 17 and 24-25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westburg in view of DE10143137, hereinafter '137. As shown in figure 3, '137 teaches the measuring chamber [as in claim 17] including a nozzle end [as in claim 25]. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the measuring chambers of '137 in the invention of Westberg, since '137 teaches the benefit of measuring parameters of medical fluid in a blood processing machine. As

for claim 25, the edge beads for the chambers and passages are shown in figure 35 of Westberg and result in a linear force. As shown in 1 and 2, '137 teaches the two part sensor modules.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of '137 as applied to claim 17 above and in further view of Odak et al. (U.S. 6,471,855). Odak teaches a cassette having a rigid base made of polypropylene (col. 9, line 8). It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the base of the cassette of the modified Westberg to be made of polypropylene as in Odak, since Odak teaches the benefit of a material suitable for cassettes.

8. Claims 19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg, as modified above, and in further view of Busby et al. (U.S. 2003/0220607). Busby teaches a cassette rigid base and membrane including polyolefin and polypropylene [0193] joined by heat sealing. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the materials of Busby in the invention of the modified Westberg, since Busby teaches the benefit of materials suitable for the construction of a medical cassette. Welding is a well-known heat sealing technique. Upon modification, regions in the cassette would be surrounded by a weld seam and could have the intended use of carrying substituates.

9. Claims 10 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg, in view of Bryant et al. (U.S. 5,474,683). As shown in figure 7, Bryant teaches a

frame having projections received within the "cutout" (the area between the flanges around the periphery of the cassette (see figure 3, adjacent the leader of 24) of the cassette. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the projections/cutout configuration of Bryant in the invention of Westberg, since Bryant teaches the benefit of retaining a cassette in a medical fluid apparatus in the desired positioned. Westberg teaches a component 42 which includes a snap-in hook such that such a modification would have been obvious to the skilled man.

10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg. Westberg teaches cassette in various configurations, e.g. 28 and 28'. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have a set of cassettes in order to have the benefit of performing a variety of different blood processing procedures in association with the device shown in figure 1 (col. 4, lines 41-44).

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of Kamen et al. (U.S. 5,628,908). Westberg teaches a venting unit of the treatment machine but doesn't teach such coupled to a gas-permeable membrane integrated into the cassette. However, such is taught by Kamen.

> The pump inlet 154 and the pump outlet 156 communicate with ambient air via a common vent 158 (shown schematically in FIG. 23). The vent 158 includes a filter (membrane) 160 that removes particulates from the air drawn into the pump 84.

As described, the filter of Kamen is permeable to gas. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the vent/filter of

Kamen as part of the venting unit of Westberg, since Kamen teaches the benefit of venting the pumps (chambers).

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of Bellotti et al. (U.S. 4,436,620). Bellotti teaches a dialyzer 38 that is integrated (forming a unit with) a cassette. The dialyzer can be grasped and could therefor be used as a handle. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the dialyzer as part of the cassette of Westberg since such would provide the benefit of a unit for ease/efficiency when installing or replacing the parts.

13. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg, as modified above, and in further view of Bilstad (U.S. 4,479,762)). As in figures 19A-19C, Bilstad teaches a substantially spherical pump chamber 134 having the modified radius to allow for a passage (it is the Examiner's position that merely naming the passage a "flush" passage fails to further limit the apparatus beyond the elements cited). It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the pump chamber of Bilstad in the invention of the modified Westberg, since Bilstad teaches the benefit of a self-contained prepackaged fluid processing module which can be conveniently stored, set-up and operated (col. 1). Also, it is contended that the line of the inlet/outlet is tangent to the curve of the pump chamber.

Response to Arguments

14. Applicant's arguments filed 5-9-2008 have been fully considered but they are not persuasive. The italicized portions in the action address Applicant's arguments. Even if Applicant amends to claim a plurality of cartridges each having a region with common sensor or actuator components and a region with unique components, such is taught by the Pastrone references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Terry K. Cecil whose telephone number is (571) 272-1138. The examiner can normally be reached on 8:00a-4:30p M-F..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mr. Terry K. Cecil/
Primary Examiner, Art Unit 1797

tkc